

linseed, iticica, tung, castor, cocoanut, palm oil, fish oil and fish liver oil.

32. The composition according to claim 25 comprising at least 50% by weight water.
33. The composition according to claim 26 comprising at least 50% by weight water.
34. The composition according to claim 27 comprising at least 50% by weight water.
35. The composition according to claim 28 comprising at least 50% by weight water.
36. The composition according to claim 29 comprising at least 50% by weight water.

Remarks

After amendment, claims 1-36 remain pending in the present applications, claims 8 and 25 having been amended to address the Examiner's 35 U.S.C. §112, second paragraph rejection. Claims 8 and 25 also have been amended to insert the term "exhibiting storage stability" within the preamble of the claim to reflect the fact that the emulsions which are claimed exhibit the unexpected characteristic of storage stability.

The original claims have been amended to address the Examiner's concerns about the previously submitted claims and compliance with 35 U.S.C. §112 and in particular, second paragraph. Claims 8 and 25 have therefore been amended. No other amendment has been made to the claims. Applicants respectfully submit that the present invention, which is directed to an unobvious combination of components which are claimed, results in an emulsion which unexpectedly exhibits storage stability. It is respectfully submitted that the claims of the instant application are now in compliance with 35 U.S.C. §112. It is noted that no claim has been amended to distinguish over the cited prior art. Support for the amendment to the claims can be

found throughout the specification and in particular, at pages 1 and 9-10.

The Examiner has rejected original claims 1-36 variously under 35 U.S.C. §112, second paragraph and §103. For the reasons which are set forth in detail hereinbelow, Applicants respectfully submit that the amended claims presented in the instant paper address the Examiner's concerns and are thus in condition for allowance.

The §112, Second Paragraph Rejection

The Examiner has rejected claims 8-36 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has questioned the use in claims 8 and 25 of terms ““actives” and medicaments” as well as the recitation of the term “vitamins, among numerous additional additives”. The Examiner has also rejected the claim for use of other terms as set forth in the August 27 office action.

Applicants have amended claims 8 and 25 accordingly, in order to address the Examiner's §112, second paragraph rejection. Each of the rejected terms has been deleted or qualified in order to address the Examiner's concerns. It is respectfully submitted that the amendment to original claims 8 and 25 of the present application now places the claims in compliance with 35 U.S.C. §112.

The §103 Rejection

The Examiner has rejected claims 1-36 as being patentable over Fogel, U.S. patent number 6,126,949 (“Fogel”), Herstein, U.S. patent number 5,902,591 (“Herstein”) and McCutcheon's Emulsifiers & Detergents North American Edition, 2000, page 18 (“McCutcheon”).

The Examiner cites Fogel for teaching component A, a dialkyl fumarate, especially dibehenyl fumarate to be useful to harden or stiffen an oil-in-water or water-in-oil emulsion and to enhance stability of water-in-oil emulsions. Fogel also is cited for teaching emollients to be used with dibehyl fumarate as petrolatum, mineral oil, various vegetable oils and neopentanoates such as octyl dodecyl neopentanoate and that the water-in-oil emulsion may contain varying amounts of water. Fogel is cited for also teaching the use of nonionic emulsifiers in water-in-oil emulsions.

Herstein is cited for teaching that a 5-10% vitamin C containing topic cosmetic composition employing several preferred emulsifiers, one of which is stearic monoethanolamide (component C). McCutcheon is cited generically for teaching the use of Arlacel P135 in cosmetics.

The Examiner readily admits that the references do not expressly teaching that the three components as claimed can be incorporated into a single composition. The Examiner also readily admits that the three references do not expressly teach the three components within the claimed weight ratios. Nonetheless, the Examiner argues that it would have been obvious to incorporate the three components into a single composition within the claimed weight ratio. Applicant respectfully strongly disagrees.

The present invention is directed to the unexpected discovery that the inclusion of a three component mixture of dialkylfumarate, polyethyleneglycol dihydroxystearate and alkyl monoethanolamide within the claimed weight ratios, when incorporated into an emulsion will provide an unexpected enhancement in the stability of the resulting emulsion. The present invention is directed to compositions which may be used to manufacture emulsions (claims 1-7), and emulsion compositions (claims 8-24) and personal care compositions (claims 25-36) which exhibit unexpected storage stability, each of which contains the three component mixture (A, B and C) within the claimed ratios. Contrary to the Examiner's contention, the cited prior art in no

way discloses or suggests the present invention.

Fogel, as indicated by the Examiner is directed to novel dialkyl fumarate compositions, which are cited for their use in dermatological products. The Examiner readily admits that Fogel does not disclose or suggest components B or C, which must be added to compositions according to the present invention *within the claimed weight ratios* in order to secure the unexpected characteristics of emulsions compositions. Although Fogel is a generally useful reference, it cannot be raised to the level of suggesting that it teaches either component B or component C of the present invention, or the weight ratios of the instant invention as set forth by the claims. Nor do the other references cited by the Examiner somehow add to Fogel to render the present invention unpatentable.

Herstein is directed to stable topical cosmetic pharmaceutical emulsions of ascorbic acid which comprise ascorbic acid, in combination with an emulsion composition containing a stabilizing effective amount of an organoclay composition. The Herstein compositions include anywhere from about 1% to about 10% by weight of the emulsifier. Of the literally thousands of disclosed emulsifiers which may be used in Herstein, one is stearic monoethanolamide. Notwithstanding the disclosure of this emulsifier, Herstein teaches that the emulsifier, in order to be effective *must be formulated* in combination with an organoclay composition. Herstein does not disclose or even suggest the use of dialkyl fumarates or polyethyleneglycol dihydroxystearate or the weight ratio which is used in the present compositions. It is respectfully submitted that Herstein adds nothing to the disclosure of Fogel which would somehow suggest to one of ordinary skill the invention of the present application.

Nor does the disclosure of McCutcheon somehow add to the disclosures of Fogel and Herstein in teaching the present invention to one of ordinary skill in the art. McCutcheon is a generic reference which discloses that Arlacel 135 is a polymeric surfactant. Noted here is the fact that McCutcheon simply provides a list of emulsifiers which are commonly available.

McCutcheon does not disclose or suggest the present invention. Indeed, McCutcheon does not even disclose that Arlacel 135 is PEG 1500 dihydroxystearate. Rather, McCutcheon simply refers to Arlacel 135 as a polymeric emulsifier available from ICI. It is respectfully submitted that McCutcheon is barely even relevant to the present invention and only in the sense that it provides a manufacturer for Arlacel 135 and indicates that Arlacel 135 may be used in skin care cosmetics and color cosmetics. Other than that meager disclosure, McCutcheon says nothing else about Arlacel 135.

It is respectfully submitted that the Examiner has not made out a cogent case that the present invention is obvious over the combined disclosures of Fogel, Herstein and McCutcheon. Instead, the Examiner's rejection simply cobbles together unrelated disclosures in the art which happen to be relevant to the present invention *only because of the existence of the present invention*. It is respectfully submitted that the Examiner's rejection is a classic case of impermissible hindsight reconstruction, the likes of which can only be made as a consequence of knowing of the present invention. It is further submitted that the Examiner's rejection is inappropriate.

Applicant respectfully submits that without the information provided in the present specification and the disclosure of the instant invention, one of ordinary skill could not possibly even combine these three isolated references, each of which refer to only a single component as claimed. Thus, Fogel may refer to dialkyl fumarate, but in no way discloses either polyethylene glycol dihydroxystearate or the alkyl monoethanolamide emulsifier. Herstein may disclose stearic monoethanolamide, but only in combination with an organoclay compound. Herstein does not disclose alkyl fumarate or polyethyleneglycol dihydroxystearate emulsifiers. McCutcheon only refers to the manufacturer of PEG 1500 dihydroxystearate, but does not provide any additional useful information. It is therefore fair to say that one of ordinary skill could not have combined the teachings of the three references when there is not even a suggestion that it is desirable to combine these components. Moreover, when taken with the fact

that the present invention requires certain weight ratios of these three emulsifiers in order to provide the claimed invention, it is simply not tenable that the claimed invention is obvious over a combination of the cited references. The Examiner is respectfully requested to withdraw this rejection as the present invention is clearly patentable.

It is respectfully submitted that Applicant has effectively addressed the Examiner's rejection of the originally filed claims under §§112 and 103, and the rejections are respectfully requested to be withdrawn.

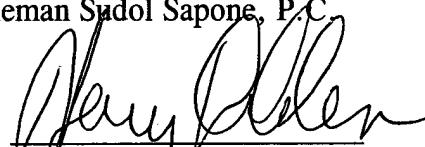
For all of the above reasons, Applicant respectfully asserts that the claims set forth in the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and indication of such allowability is earnestly solicited.

Applicants have neither cancelled nor added any claim. No fee is therefore due for the presentation of this amendment. If any fee is due please charge Deposit Account No. 04-0838. An appendix indicating the amendments made to the previously submitted claims is attached hereto.

Respectfully submitted,

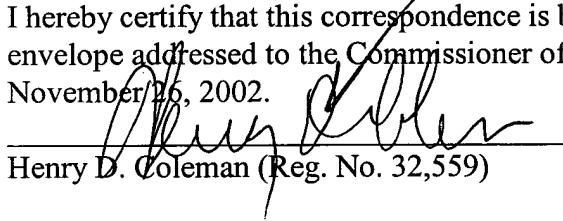
Coleman Sudol Sapone, P.C.

November 26, 2002

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I hereby certify that this correspondence is being sent by First Class Mail in an envelope addressed to the Commissioner of Patents, Washington, D.C. 20231 on November 26, 2002.


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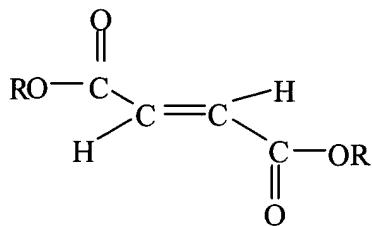
Appendix of Amended Claims

Claims 8 and 25 are amended as follows. All other claims remain unamended.

Claims 1-7 remain unamended.

8. (Amended) A composition in the form of an emulsion exhibiting storage stability comprising:

a) about 1% to about 15% by weight of a dialkyl fumarate according to the structure:



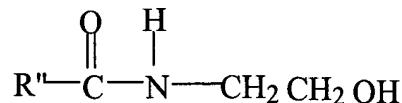
where R is a C₁₂-C₂₂ linear or branch-chained alkyl group as component A of said mixture;

b) about 1% to about 15% by weight of a polyethyleneglycol dihydroxystearate according to the structure:



where R' is a 12-hydroxystearoyl group and X is an integer from 16 to 60, as component B of said mixture;

c) about 1% to about 15% by weight of an alkyl monoethanolamide according to the structure:



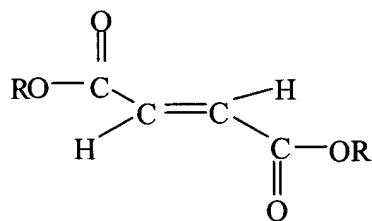
where R" is a C₁₁-C₂₁ linear or branch-chained alkyl group as component C of said mixture;

d) about 5% to about 85% by weight of an emollient oil;
e) about 10% to about 90% by weight water; and
f) optionally, about 0.05% to about 50% by weight of an additive selected from the group consisting of surfactants, conditioning agents, coloring agents, pigments, fragrances, humectants, preservatives, anti-oxidants, [and] oil and water soluble ["actives" and] medicaments, [including vitamins, among numerous additional additives, including] deodorant compounds, anti-perspirant compounds[, including salts, among others] and mixtures thereof ;
with the proviso that the weight ratio of any one of said components A, B and C in said emulsion composition is no greater than about 3 times and no less than about 1/3 the weight ratio of any other component A, B and C in said emulsion composition.

Claims 9-24 remain unamended.

25. (Amended) A personal care composition in the form of an emulsion exhibiting storage stability comprising:

a) about 1% to about 15% by weight of a dialkyl fumarate according to the structure:



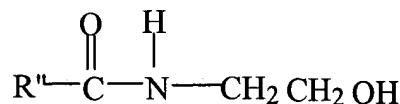
where R is a C₁₂-C₂₂ linear or branch-chained alkyl group as component A of said mixture;

b) about 1% to about 15% by weight of a polyethyleneglycol dihydroxystearate according to the structure:



where R' is a 12-hydroxystearoyl group and X is an integer from 16 to 60, as component B of said mixture;

c) about 1% to about 15% by weight of an alkyl monoethanolamide according to the structure:



where R" is a C₁₁-C₂₁ linear or branch-chained alkyl group, as component C of said mixture;

- d) about 5% to about 85% by weight of an emollient oil;
- e) about 10% to about 90% by weight water; and
- f) about 0.5% to about 50% by weight of at least one additive selected from the group

consisting of surfactants, skin and hair conditioning agents, coloring agents, pigments, fragrances, humectants, preservatives, anti-oxidants, oil and water soluble [actives and] medicaments, deodorant compounds, antiperspirant compounds, and mixtures thereof, with the proviso that the weight ratio of any one of said components A, B and C in said emulsion composition is no greater than about 3 times and no less than about 1/3 the weight ratio of any other component A, B and C in said emulsion composition.

Claims 26-36 remain unamended.